

B1

3 a local anaesthesia assembly for producing a reversible loss of
4 sensation in a surgical area proximate to a vertebral body;
5 a cement assembly for preparation of a hardenable liquid biomaterial
6 for strengthening said vertebral body;
7 a surgical cutting instrument for providing cutaneous incision in said
8 surgical area proximate to said vertebral body; and
9 a device for injection of said hardenable liquid biomaterial into said
10 vertebral body.

Subcl B2

Amend Claim 14 as follows:

1 14. (Amended) A cement assembly according to claim 11, wherein said
2 polymer powder in said hardenable liquid biomaterial is from about five grams
3 to about forty grams of methylemethacrylate.

Subcl B3

Amend Claim 17 as follows:

1 17. (Amended) A kit for use in performing vertebroplasty, said kit
2 comprising:
3 a first tray of components for performing a first vertebroplasty
4 injection through a first pedicle of a vertebral body;
5 a second tray of components for performing a second vertebroplasty
6 injection through a second pedicle of said vertebral body, such that said
7 second tray of components can remain sterile for use in another vertebral
8 body if said first vertebroplasty injection sufficiently strengthens said
9 vertebral body.

Remarks

In the Office action of August 8, 2002, Paper No. 9, claims 1-21 are pending and were rejected. In addition, the drawings were objected to because they did not include certain figures mentioned in the description. In particular, with

respect to the claims, claims 14 and 17-19 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter sought to be patented. Claims 17-19 were also rejected under 35 U.S.C. 102(b) as being anticipated by Lazarus. Claims 17-18 were further rejected under 35 U.S.C. 102(b) as being anticipated by Partika, Claims 1-16, 20 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Folkman in view of Shanley, Macleod, Smith, Arlers, Racz, Jiang, Singer, Draenert, Haynie, Hertzman, and Baker.

By this amendment, claims 1, 14 and 17 are being amended to more particularly point out and distinctly claim the subject matter sought to be patented. In particular, claim 1 is being amended to indicate that the cement assembly is "for" strengthening "said" vertebral body. In addition, the Examiner's attention is drawn to lines 4 and 8 to "a hardenable liquid biomaterial" which forms the antecedent basis for the same in dependent claim 14. In dependent claim 14, "polymer," is being changed to correspond to "polymer powder" in dependent claim 11. The amendment of claim 1 should have addressed the antecedent basis problem in claim 14. In independent claim 17, antecedent basis is being established for the first pedicle by changing "the" to "a." In addition, the claim is being amended to include that the second tray of components is "for" performing a second vertebroplasty "injection" through "a" second pedicle of said vertebral body and that "said" second tray of components can remain sterile As a result of the amendments to claims 1, 14 and 17, applicant's request that the rejections of claims 14 and 17, as amended herein, and claims 18 and 19 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter sought to be patented, be withdrawn. Applicant traverses the rejection of claims 17-19 under 35 U.S.C. 102(b) as being anticipated by Lazarus or Partika and the rejection of claims 1-16, 20 and 21 under 35 U.S.C. 103(a) as being unpatentable over Folkman in view of Shanley, etc.

Enclosed herewith is a copy of the letter to the official draftsman transmitting two sheets of drawings for Figs. 2 and 3 to overcome the objection to the drawings. These two sheets of drawings for Figs. 2 and 3 depict what is

detailed in the two paragraphs bridging pages 4 and 5 of the specification. In addition, a brief description of the drawings is included on page 3, lines 23-26. Applicant's submit that the drawing and corresponding description provided in the specification are merely providing anatomical background and not directly relevant to the claimed invention other than specifying the anatomical site. Furthermore, these two sheets of drawings were included in the claimed priority Canadian Application No. 2,287,112, filed October 29, 1999 and in parent U.S. Parent Application, Ser. No. 09/425,480, filed October 22, 1999. Applicant submits that submission of these two figures of the drawing is merely a depiction of what is already in the specification and does not constitute the inclusion of any new subject matter. In view thereof, applicant requests approval from the Examiner to include these two figures in the drawing and to remove the objection to the drawing.

With respect to the rejection of claims 17-19 under 35 U.S.C. 102(b) as being anticipated by Lazarus and Partika, applicant's invention is directed to a kit for use in performing a vertebroplasty medical procedure. The kit comprises a first tray of components for performing a first vertebroplasty injection through a first pedicle of a vertebral body and a second tray of components for performing a second a second vertebroplasty injection through a second pedicle of the vertebral body. The kit is configured so that the second tray of components can remain sterile for use with another vertebral body if the first injection sufficiently strengthens the initial vertebral body. In addition, the kit is directed to performing a particular medical procedure such as a vertebroplasty.

Lazarus is directed to a peritoneal fluid treatment, which is an entirely different medical procedure from that of a vertebroplasty medical procedure. Lazarus discloses a package 10 containing a conventional intravascular catheter 12, a wire guide 14 and an elongated cannula 16 for performing the peritoneal fluid treatment medical procedure. These three items are included in separate packages 90, 92 and 94, which can be viewed through a transparent side of the package. These items are included in package half 10A, which is separately sealable and openable and separable from package half 10B, which includes surgical items for preparing the patient for the peritoneal fluid treatment procedure. Should package

half 10B not be needed to prep the patient, it can be separated from package half 10A and used in another fluid treatment procedure.

Partika discloses a skin preparation tray 10 which may be configured as a removable component of surgical kit 12. Surgical kit 12 includes various implements 14; however, no particular medical procedure is indicated. Partika, like Lazarus, includes a tray for skin preparation and a separate tray for performing a given medical procedure. Applicant's invention is directed to a kit in performing vertebroplasty of which each tray of components is directed to the same medical procedure should the second tray be needed to complete the vertebroplasty procedure.

In view of the above, applicant submits that the kit for use in performing vertebroplasty is not identically disclosed in either of the Lazarus or Partika references. Furthermore, the two trays of components for performing the vertebroplasty are complementary in that the second tray is utilized should the first tray of components not be sufficient to complete the vertebroplasty procedure. Such is not identically disclosed in the Lazarus or Partika references, particularly where both references are directed to a kit including a skin preparation component tray and a separate set of components for performing another or non-specified medical procedure. As a result, applicant submits that independent claim 17, as amended herein, and dependent claims 18 and 19 are not identically disclosed by Lazarus or Partika, and it is requested that the rejection of these claims under 35 U.S.C. 102(b) as being anticipated by Lazarus or Partika, be withdrawn.

With respect to the rejection of claims 1-16, 20 and 21, under 35 U.S.C. 103(a) as being unpatentable over Folkman in view of Shanley, etc., applicant submits that none of the cited references are directed to performing a vertebroplasty medical procedure. Using unpermitted hindsight, the Examiner has simply taken applicant's claimed kit of components for use in performing vertebroplasty and utilized the elements thereof as a grocery list in finding the individual elements of applicant's claims in a series of unrelated references. There is absolutely no suggestion or motivation in any of the selected references to form a kit as claimed in applicant's invention. Therefore, the Examiner has failed to

establish a prima facie case of obviousness. In view thereof, applicant submits that claims 1 and 14, as amended herein, and claims 2-13, 15, 16, 20 and 21 are not taught or even suggested by any of the cited references, and it is requested that the rejection of these claims under 35 U.S.C. 103(a) as being unpatentable over Folkman in view of Shanley, etc., be withdrawn.

Enclosed is a Petition and Fee for Extension of Time (one month).

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

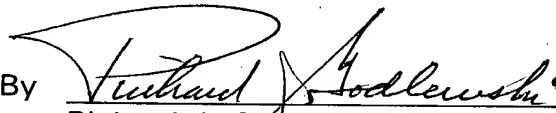
Respectfully submitted,

Kieran P.J. Murphy, M.D.

Date:

Dec. 9, 2002

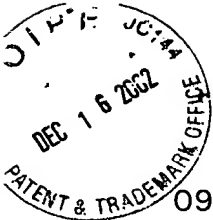
By



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Enclosures:

Transmittal of New Drawings to Overcome Objection.
(2 new sheets)
Marked Up Copy of Amended Claims (1, 14 and 17)
Petition and Fee for Extension of Time



09/594,685

Marked-up Copy of Amended Claims

Patent

1. A tray of components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia assembly for producing a reversible loss of sensation in [the] a surgical area proximate to a vertebral body;

a cement assembly for preparation of a hardenable liquid biomaterial for strengthening [of a] said vertebral body;

a surgical cutting instrument for providing cutaneous incision in [a] said surgical area proximate to said vertebral body; and

a device for injection of [the] said hardenable liquid biomaterial into said vertebral body.

14. A cement assembly according to claim 11, wherein said polymer powder in said hardenable liquid biomaterial is from about five grams to about forty grams of methylemethacrylate.

17. A kit for use in performing vertebroplasty, said kit comprising:

a first tray of components for performing a first vertebroplasty injection through [the] a first pedicle of a vertebral body;

a second tray of components for performing a second vertebroplasty injection through [the] a second pedicle of [a] said vertebral body, such that said second tray of components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body.

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